



Docket No. 1829-4004US1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): SUSAN A. SLAUGENHAUPT, ET AL.

Group Art Unit: 1645

Serial No.: 10/041,856

Examiner: Not Yet Assigned

Filed: January 7, 2002

For: GENE FOR IDENTIFYING INDIVIDUALS WITH FAMILIAL DYSAUTONOMIA

**EXPRESS MAIL CERTIFICATE**

Mail Stop \_\_\_\_\_  
Commissioner for Patents  
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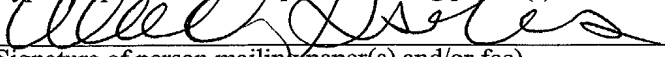
I hereby certify that the following attached paper(s) and/or fee

1. Information Disclosure Statement;
2. PTO-Form 1449 w/copies of all cited references;
3. A copy of the International Search Report;
4. A return receipt postcard.

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Albert Isles

(Typed or printed name of person mailing papers(s) and/or fee)

  
(Signature of person mailing paper(s) and/or fee)

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07-21-03

GR1645

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**INFORMATION DISCLOSURE STATEMENT**

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Commissioner for Patents  
P.O. Box 1450  
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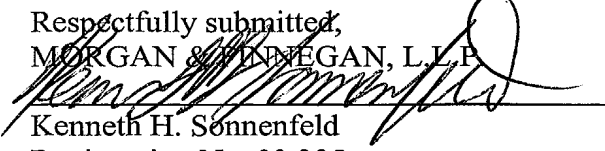
TECH CENTER 1600/2900

Sir:

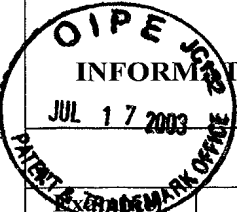
Pursuant to Rule 56, applicant hereby calls the attention of the Patent Office to the references listed on the attached Form PTO 1449. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) \_\_\_\_\_, filed \_\_\_\_\_, respectively.

- ☐ This document is being filed within three (3) months of the filing date of the application
- ☐ Please charge the \$180 fee to Deposit Account No. 13-4500, Order No. \_\_\_\_\_.
- ☐ This document is being concurrently filed with the above-identified application
- ☐ This document is being concurrently filed with an Request for Continued Examination (RCE)
- ☒ This document is being filed prior to a first Office Action
- ☒ This document is accompanied by a Search Report/Communication cited in a corresponding PCT or foreign counterpart application.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500, Order No. 1829-4004US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Dated: July 17, 2003

Respectfully submitted,  
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By:   
Kenneth H. Sonnenfeld  
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 <p><b>FORM PTO-1449</b> <b>INFORMATION DISCLOSURE CITATION</b></p>			Attorney Docket: 1829-4004US1		Serial No.: 10/041,856	
			Applicant: Susan Slaugenhaupt, et al.			
			Filing Date: January 7, 2002		Group Art Unit: TBA	
<b>U.S. PATENT DOCUMENTS</b>						
Initial	Patent Number	Publication Date	Name	Class	Sub-Class	Filing Date
	5,387,506	02/07/95	A. Blumenfeld, et al.	435	6	5/29/92

<b>FOREIGN PATENT DOCUMENTS</b>						
Examiner Initial	Patent Number	Publication Date	Country	Class	Sub-Class	Translation
	WO 99/25730	5/27/99	PCT	C07 K	7 / 06	N / A
	EP 1 225 232 A2	7/24/02	Europe	C12 Q	1 / 68	N / A
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No

<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, etc.)</b>	
	L. Cohen, et al., "IKAP is a scaffold protein of the I B kinase complex," <u>Nature</u> , 395:292-296, 17 September 1998.
	S. A. Slaugenhaupt, et al., "Tissue-Specific Express of a Splicing Mutation in the <i>IKBKAP</i> Gene Causes Familial Dysautonomia," <u>Am. J. Hum. Genet.</u> , 68:598-605, 2001.
	S. A. Slaugenhaupt, et al., Database EMBL 'Online! EBI; "Homo sapiens IkappaBkinase complex-associated protein (IKBKAP) mRNA," retrieved from <a href="http://www.EBLAC.UK">HTTP://www.EBLAC.UK</a> , Database accession no.: AF153419, 2 January 2001 updated February 28, 2001.
	S. L. Anderson, et al., "Familial Dysautonomia is Caused by Mutations of the IKAP Gene," <u>Am. J. Hum. Genet.</u> , 68: 753-758, 2001.

<b>Examiner</b>	<b>Date Considered</b>
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	



## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>1829-4004PC</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 02/ 00473</b>	International filing date (day/month/year) <b>07/01/2002</b>	(Earliest) Priority Date (day/month/year) <b>06/01/2001</b>
Applicant <b>DYSAUTONOMIA FOUNDATION INC.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. (With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure .

☐ because this figure better characterizes the invention.

☒ None of the figures.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 02/00473

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/68 C07K14/47 C12N15/63 C12N15/10 A01K67/027

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, EMBL, MEDLINE, EMBASE, PAJ, BIOSIS, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>COHEN L HENZEL W J BAEUERLE P A: "IKAP is a scaffold protein of the IkappaB kinase complex"</p> <p>NATURE, MACMILLAN JOURNALS LTD. LONDON, GB,</p> <p>vol. 395, 17 September 1998 (1998-09-17), pages 292-296, XP002956454</p> <p>ISSN: 0028-0836</p> <p>cited in the application</p> <p>page 296, left-hand column, paragraph 3</p> <p>-right-hand column, paragraph 3</p> <p>figure 2</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	<p>1,2,6,8,</p> <p>10-13,</p> <p>29,30,43</p>

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*G\* document member of the same patent family

Date of the actual completion of the international search

2 June 2003

Date of mailing of the international search report

24/06/2003

Name and mailing address of the ISA

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Authorized officer

Ulbrecht, M

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/00473

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>W0 99 25730 A (TULARIK INC) 27 May 1999 (1999-05-27)</p> <p>page 8, line 6 -page 9, line 29 claims 1-5 SEQ ID Nos. 1 and 2</p>	1,2,6,8, 10-13, 29,30,43
X	<p>DATABASE EMBL 'Online! EBI; 2 January 2001 (2001-01-02) SLAUGENHAUPT S.A. ET AL.: "Homo sapiens IkappaBkinase complex-associated protein (IKBKAP) mRNA" retrieved from HTTP://WWW.EBI.AC.UK Database accession no. AF153419 XP002240942 the whole document</p>	1,2,6,8, 10-13, 29,30,43
P,X	<p>SLAUGENHAUPT SUSAN A ET AL: "Tissue-specific expression of a splicing mutation in the IKBKAP gene causes familial dysautonomia" AMERICAN JOURNAL OF HUMAN GENETICS, AMERICAN SOCIETY OF HUMAN GENETICS, CHICAGO, IL, US, vol. 68, no. 3, March 2001 (2001-03), pages 598-605, XP002188142 ISSN: 0002-9297 the whole document</p>	1-43
P,X	<p>ANDERSON S L ET AL: "FAMILIAL DYSAUTONOMIA IS CAUSED BY MUTATIONS OF THE IKAP GENE" AMERICAN JOURNAL OF HUMAN GENETICS, AMERICAN SOCIETY OF HUMAN GENETICS, CHICAGO, IL, US, vol. 68, no. 3, March 2001 (2001-03), pages 753-758, XP009005056 ISSN: 0002-9297 the whole document</p>	1-43
E	<p>EP 1 225 232 A (ANDERSON SILVIA L ;RUBIN BERISH Y (US)) 24 July 2002 (2002-07-24)</p> <p>the whole document</p>	1-9,15, 20, 28-30, 42,43
A	<p>US 5 387 506 A (BLUMENFELD ANAT ET AL) 7 February 1995 (1995-02-07) the whole document</p>	1-43

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/00473

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9925730	A	27-05-1999	US 5891719 A AU 1525499 A WO 9925730 A1 US 6172195 B1	06-04-1999 07-06-1999 27-05-1999 09-01-2001
EP 1225232	A	24-07-2002	CA 2366046 A1 EP 1225232 A2 US 2002168656 A1	17-07-2002 24-07-2002 14-11-2002
US 5387506	A	07-02-1995	AU 4390293 A CA 2136859 A1 GB 2282446 A ,B IL 105818 A IL 120076 A WO 9324657 A2 US 6262250 B1 US 5998133 A US 2002025528 A1 ZA 9303670 A	30-12-1993 09-12-1993 05-04-1995 04-01-1998 28-10-1999 09-12-1993 17-07-2001 07-12-1999 28-02-2002 01-08-1994

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 34,35

Present claims 34 and 35 relate to a product defined by reference to a desirable characteristic or property, namely oligonucleotides which hybridise to one or more additional mutant or wild-type genes associated with additional genetic diseases. The claims cover all products having this characteristic or property, whereas the application provides neither support within the meaning of Art. 6 PCT nor disclosure within the meaning of Article 5 PCT for any such product. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search is impossible. Independent of the above reasoning, the claims also lack clarity (Art. 6 PCT). An attempt is made to define the product by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the subject-matter of claims 34 and 35 has not been searched at all.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 02/00473

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 34, 35  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.